K122909

DEC 2 7 2012

510(K) SUMMARY

FOR

syngo® Single Source Dual Energy

Submitted by:

Siemens Medical Solutions USA, Inc.

51 Valley Stream Parkway

Malvern, PA 19355

September 14, 2012

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

1. **Contact Person:**
Mrs. Kimberly Mangum
Technical Specialist, Regulatory Affairs Submissions
Siemens Medical Solutions, Inc. USA
51 Valley Stream Parkway D02
Malvern, PA 19355-1406
Phone: (610) 448-4912 Fax: (610) 448-1787
Email: kimberly.mangum@siemens.com

2. **Device Name and Classification**

Product Name:	***syngo® Single Source Dual Energy***
Propriety Trade Name:	***syngo® Single Source Dual Energy***
Classification Name:	Accessory to Computed Tomography X-ray System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1750
Device Class:	Class II
Product Code:	90JAK

3. Substantial Equivalence:

Siemens ***syngo® Single Source Dual Energy*** is substantially equivalent to the following medical device in commercial distribution:

Predicate Device Name	***FDA Clearance Number***	***FDA Clearance Date***
syngo® Dual Energy with extended functionality	K083524	04/01/2009
syngo® Volume Perfusion - CT Body	K073373	12/18/2007

4. Device Description:

Dual Energy CT can be used to obtain intensity measurements with two different spectra and thus provides additional information when compared to single energy.

This additional information is analyzed in the post processing application *syngo® Single Source Dual Energy* and can be used to improve the visualization of various materials in the human body.

After loading the reconstructed images corresponding to the two subsequent scans with different X-ray spectra into *syngo® Single Source Dual Energy,* the images are first registered to compensate for motion effects. They are then displayed using linear blending with selectable mixing ratio and color scale ("General Viewing"). Multiplanar reformations (MPR) of the volume are shown in 3 image segments, which are initialized as sagittal, coronal and axial view.

After arriving at an initial diagnosis on the basis of the CT-images, the user can choose between application classes Monoenergetic or Gout Evaluation.

These application classes are designed for specific clinical tasks, so that algorithms, additional tool buttons, the use of colored overlay images and image representation (for example MPR or maximum intensity projection) are optimized correspondingly. For Gout Evaluation a fourth image segment is used for volume rendering techniques (VRT). It is possible to adjust Gout Evaluation by using a configuration dialog. Special tools are available to remove the table or perform manual punching.

5. Summary of Technical Characteristics of the Subject Device as Compared with the Predicate Device:

syngo® Single Source Dual Energy software package provides the same and unmodified application classes as the predicate devices. The unmodified algorithm for motion correction as used in syngo® Volume Perfusion Body was added to allow the evaluation of images achieved with single source scanners and reduce motion effects in images from dual source scanners.

syngo® Single Source Dual Energy does not have significant changes in materials, energy source, or technological characteristics when compared to the predicate devices. The intended use and fundamental scientific technology are similar to the predicate devices; therefore Siemens believes that they are substantially equivalent to the predicate devices.

6. Nonclinical Testing:

syngo® Single Source Dual Energy software package uses the same algorithm for non rigid registration as syngo® Volume Perfusion – CT Body. This algorithm is unmodified since the release of syngo® Volume Perfusion-CT Body and in clinical use since that time without any known problems.

The verification and validation was performed for all newly developed components and the complete software package, according the following standards:

DICOM, NEMA PS 3.1 - 3.18 (2008),
IEC 60601-1-4: Ed. 1.1.2000
IEC 60601-1-6: 2004
IEC 62304 Ed. 1.0, 2006
IEC/ISO 14971 (2007)

After completion of the test and comparison of the test results with the release acceptance criteria, Siemens is of the opinion, that syngo Single Source Dual Energy is substantially equivalent to the predicate devices.

7. Indications for Use:

syngo® Single Source Dual Energy is designed to operate with CT images taken at the same anatomical region of a patient using two different kV levels. The differences in the energy dependence of the attenuation coefficient of the different materials provide information about the chemical composition of body materials. The images are combined to

visualize and analyze information about anatomical and pathological structures.

The functionality of the *syngo Single Source Dual Energy* applications are as follows:

- Gout Evaluation
- Monoenergetic

8. **General Safety and Effectiveness Concerns**:

The device labeling contains instructions for use and any necessary cautions and warnings to provide for safe and effective use of the device.

Risk management is ensured via a hazard analysis, which is used to identify potential hazards. These potential hazards are controlled during development, verification and validation testing. To minimize electrical, mechanical, and radiation hazards, Siemens adheres to recognized and established industry practice and standards.

In summary Siemens is of the opinion, that *syngo Single Source Dual Energy* software package does not introduce any new potential safety risks and is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Siemens Medical Systems, Inc.
Kimberly Magnum
51 Valley Stream Parkway
MALVERN PA 19355-1406

December 27, 2012

Re: K122909
Trade/Device Name: *syngo* Single Source Dual Energy
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-ray System
Regulatory Class: Class II
Product Code: JAK
Dated: Nov. 30, 2012
Received: Dec. 7, 2012

Dear Ms. Mangum:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Michael D. O'Hara

Janine M. Morris
Director
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122909

Device Name: *syngo® Single Source Dual Energy*

Indications For Use:

syngo® Single Source Dual Energy is designed to operate with CT images taken at the same anatomical region of a patient using two different kV levels. The differences in the energy dependence of the attenuation coefficient of the different materials provide information about the chemical composition of body materials. The images are combined to visualize and analyze information about anatomical and pathological structures.

The functionality of the *syngo® Single Source Dual Energy* applications are as follows:

- Gout Evaluation
- Monoenergetic

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health

510(k) K122909